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08/722,144	12/12/96	ISHIGURO	222200000

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BERCH, H EXAMINER

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ART. UNIT	PAPER NUMBER
1011	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 08/722,144	Applicant(s) Ishiguro
Examiner Mark L. Berch	Group Art Unit 1611

Responsive to communication(s) filed on 7/7/98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

- Claim(s) 1-35 and 37-68 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) 35 is/are allowed.
- Claim(s) 1-34 and 37-68 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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DETAILED ACTION

*Claim Rejections - 35 USC § 102 and 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 69373.

The reasons were given previously; the traverse on this point is unpersuasive. The racemate (at the 1' position; the other two positions are the same as in the claims) does indeed anticipate. The claim merely requires that the claimed compound be present. It does not forbid the presence of other materials. A product which consists of the claimed compound mixed with air, a carrier, another enantiomer, etc, would still infringe this claim. As noted, page 11 names a species; it is irrelevant whether the species was or was not prepared; the name alone is enough to put it into the public domain. Moreover, applicants' exact (1'S, 5R, 6R) configuration is seen, as noted, at page 17, line 27, and in examples 4, 6, 7, 8, and 12..

Claims 1, 33, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afonso.

The reasons were given previously; the traverse on this point is unpersuasive. As stated, the compounds are homologues. Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders

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*prima facie* obvious its homologue. The homologue is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness.

Applicants respond that “it is known that” if the 1'R isomer has an ethyl or higher tail, it is “no longer equipped with any substantial activity.” Applicants have presented no evidence for this fact, nor have they presented any evidence why this would be expected to be true for the compounds with the (1'S, 5R, 6R) configuration. Moreover, applicants have presented no direct comparison to the prior art species, and hence are in no position to assert unexpected effects.

Claims 1,17-19, 32-34, 54-56 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girijavallabhan.

The reasons were given previously; the traverse on this point is unpersuasive. Compound 23 is indeed cis. This compound is a homolog, and hence the same reasoning applies. Note that Claim 35 is no longer rejected.

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Claims 1-34 and 37-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiguro.

The reasons were given previously; the traverse on this point is unpersuasive.

The exact same issue arises here.

Claims 1-4, 7-19, 31-34, 37-57, 60, 63, 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa.

The reasons were given previously; the traverse on this point is unpersuasive.

The same issues apply. Applicants ask, "Why would one skilled in the art be led to the (1'S, 5R, 6R) configuration..." Its not merely a matter of being led; the (1'S, 5R, 6R) configuration is directly taught as noted, in Ex 1-4, 33, 43-45 and 50.

Claims 1, 30, 31, 33, 37, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menard et al.

The reasons were given previously; the traverse on this point is unpersuasive. The reference does indeed teach alkyl generically; a reference is not limited to what is labeled as preferred.

Claims 1-32, and 37-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leanza.

The reasons were given previously; the traverse on this point is unpersuasive. This side chain is preferred as shown at Column 18, line 26 and again at Column 19, line 50, and appears in examples 83-89, and the 5R, 6R configuration is present as noted in column 23. Applicants correctly observe that both features are not shown in

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the same molecule, but this is tantamount to saying that the reference is not an anticipation. That is true, but this is a rejection for obviousness.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718.



Mark L. Berch

Primary Examiner

Group 1610 - Art Unit 1611

August 12, 1998